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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,346	03/25/2004	Alexander Medvedev	033954-002	5447
21839	7590	10/26/2005	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404				PATEL, JOY
ART UNIT		PAPER NUMBER		
				3766

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/808,346	MEDVEDEV, ALEXANDER	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joy P. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 March 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-7,10-12,14-16,19 and 20 is/are rejected.
- 7) Claim(s) 4,8,9,13,17,18 and 21-23 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/25/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

**DETAILED ACTION*****Drawings***

1. The drawings are objected to because element 304 in figure 1 is defined as the left ventricle in the specifications, but is clearly labeling the left atrium in the figure. Furthermore, element 310 in figure 1 is not labeled, and should be labeled "pump". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed

of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

2. The disclosure is objected to because of the following informalities: on paragraph 24, element 410 is mentioned in the specifications, but not depicted in the figure (figure 4). Figure 4 only depicts elements 410a, 410b, 410c, and 410d.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3, 5, 6, 12, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 3 and 12, these claims define M as a function of N; however the function f(N) is not defined in any of the previous claims, nor is it defined in the specifications. Therefore, the claim is not enabling.

Claims 5, 6, 14, and 15 are rejected as being dependent upon a rejected base claim 3.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 7, 10, 11, 16, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Medvedev et al. (US 2004/0152944 A1).
5. In regard to claim 1, Medvedev discloses, "Three feedback channels, one for each of voltage, current, and motor speed lead to a microcontroller or microprocessor (18). The three feedback waveforms are analyzed and from these waveforms, motor input power, patient heart rate...are determined" (Abstract, lines 3-9). Therefore the speed values and heart rate are determined by the pump. Medvedev further discloses, "The microprocessor (18) then calculates a desired flow rate proportional to the patient heart rate" (Abstract, lines 9-10). Since the flow rate is dependent upon the speed of the motor, the speed is therefore also proportional to the heart rate. Medvedev further discloses, "The microprocessor communicates a new power output...which regulates the power to the

motor (12)" (Abstract, lines 10-12). Therefore, the speed of the pump, which is regulated by the motor, is adjusted in accordance with the desired speed to heart rate ratio.

6. In regard to claim 2, Medvedev discloses, " $\phi$  is a monotonic function within the pump operating range" (Paragraph 38, line 3). Since Q has a linear correlation with  $\phi$ , the speed of the pump is regulated to achieve a target flow rage (Q) that is a monotonic function of said ratio within a defined range of flow rates. The target flow rate (Q) is a function of the previously mentioned ratio because it is still dependent on  $\omega^2$ , which is the square of the angular velocity (speed) of the pump and the speed is proportional to the heart rate (See equation 4). See also page 2, paragraph 36, line 1 and paragraph 31.
7. In regard to claim 7, Medvedev discloses, "An additional indicator of either a suction or a pre-suction condition is the absolute value for flow pulsatility..." (Paragraph 63), which he defines as absDQ. Medvedev goes on to disclose, "Any absDQ values below a predetermined limit, can be used to detect such conditions and require an immediate pumping power reduction" (Paragraph 64, lines 4-6).
8. In regard to claim 10, Medvedev discloses, "In the preferred embodiment, the blood pump 10 is an implanted centrifugal blood pump" (Paragraph 45, lines 2-4). In figure 6, Medvedev further discloses, "A power supply 14 supplies power to the motor 12 via a motor winding commutation circuit 16. The circuit 16 acts as a power regulator and is controlled by a

microprocessor or microcontroller 18" (Paragraph 45, lines 5-8). Also see rejections for claim 1.

9. In regard to claim 11, see the rejection for claim 2. Furthermore, it can be seen from the abstract, lines 3-12, that the microprocessor controls the speed of the pump. Therefore, the microprocessor does regulate the speed of the pump to achieve a target flow rate (Q) that is a monotonic function of said ratio within a defined range of flow rates.
10. In regard to claim 16, see rejection for claim 7. Furthermore, it can be seen from the abstract, lines 3-12, that the microprocessor controls the speed of the pump. Therefore, the microprocessor (controller) changes the pump speed when flow pulsatility falls below a first threshold.
11. In regard to claim 19, Medvedev discloses a microcontroller that regulates the speed of the blood pump (See Figure 6). See also rejection for claim 1, regarding the ratio of the patient's heart rate to the speed of the pump. Furthermore, the microprocessor contains a computer program as is disclosed by Medvedev in paragraph 41, line 1. Here, Medvedev discloses that a software failure can occur. Since all computer programs are software, the microprocessor contains a computer program.
12. In regard to claim 20, see rejections for claims 11, and 19.

#### ***Allowable Subject Matter***

13. Claims 4, 8, 9, 13, 17 18, 21, 22, and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten

in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 3, 5, 6 and 12, 14, and 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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